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EXAMINER

HOLMES, REX R

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/781,357

Applicant(s)

HEGDE ET AL.

Examiner

Rex Holmes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
4a) Of the above claim(s) 2-3, 35-42 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 4-34 and 43-49 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/14/04;9/29/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1 and 4-34 and 43-49 in the reply filed on 9/08/06 and 11/10/06 is acknowledged. Applicant stated in page 2 of the reply filed on 11/10/06 that the claims readable on the elected species include claims 1-34 and 43-49. On page 1 of the reply the applicant elected from species group A, ion exchange polymer metal composite. Based on this election, claims 2 and 3 are not readable on the elected species.
2. Claims 2-3, 35-42 and 50-196 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/08/06 and 11/10/06.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 14-16, 31 and 44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claim 1, line 4 recites the limitation, "a body lumen", this is vague and unclear as it is uncertain whether this body lumen is different from the body lumen recited in the preamble. If the applicant is referencing the same body lumen, it is suggested that the applicant change "a body lumen" to "said body lumen".

7. Claims 14 and 15 recite the limitation, "... wherein during activation of the first layer..." Claims 14 and 15 are incomplete for omitting an element to activate the first layer.

8. Claims 16 and 44 are vague and unclear as an applicant can not claim a body part. It is suggested to phrase the claim in a functional use recitation relative to a claimed element.

9. Claim 31 is vague and unclear as it does not further limit the claim from which it depends. Claim 31 recites "... the second layer further comprising..." It is suggested to insert the term "wherein" before "the second layer..."

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 4, 6-9, 17-34, 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Banik (U.S. Pub. 2003/0212306 A1).

12. Regarding claims 1, 4, 6-9, 16-34 and 43-44, Banik discloses an electroactive polymer based sphincter that comprises a polymer layer and a stiffer metal electrode layer of sufficient length to encircle a body lumen and is capable of encircling an aorta (e.g. Figs. 1-5c). Banik further discloses an ion-exchange metal composite wherein the electrode is made from any metal including silver and gold (e.g. Figs. 1-5c; ¶ 89). Banik also discloses an anode (118), a cathode (112), a elastomer layer between (114). Banik further discloses insulating layers (110 & 120) that are located adjacent to both the anode and the cathode.

13. Banik further discloses that the device forms a cuff that fully encircles a body cavity (e.g. Fig. 8A). Banik also discloses that the cuff strap shaped so that it is bent in a "c" shape to encircle the lumen and includes suture holes (¶¶ 70-71) or ends that clasp together with a mating fastener to form a positive lock to fit around a lumen (e.g. Fig. 4, ¶). Banik also discloses that it has a third layer (122) that acts as a graft layer made of polymeric materials that cause tissue growth (e.g. ¶¶ 93, 124). It is also disclosed that the second layer may contain a structural element that is used as a restoring force and can be made of any biocompatible material (¶¶ 26 and 93-94).

14. Examiner notes the limitation, "... wherein the body lumen is selected from the group consisting of: the aorta..", is only functional language and only requires the capability to so perform. Here the electroactive polymer as suggested by Banik is capable of being used on the aorta.

15. It is noted that all paragraphs and images listed in this document are approximations as to the areas in the reference(s) as to where the disclosed information is located. The reference may include other disclosures and should be read in whole.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claim 5, 10-13, 16, 44-49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banik.

19. Regarding claim 5, Banik discloses the claimed invention except for the isomer for the ion-exchange polymer metal composite being chosen from the group of; perfluorosulfate, perfluorocarboxylate, polyvinylidene fluoride or any combination thereof. It would have been obvious to one having ordinary skill in the art at the time

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the invention was made to modify the device as taught by Banik, with a ion-exchange polymer from the list above since it was known in the art that there are only a few isomers that can be used to provide ion-exchange polymer metal composites and that these isomers are used to provide large motion actuators.

20. Regarding claims 10-13, Banik discloses the claimed invention except for ranges for the anode/cathode conductivity, elastomer dielectric strength, hardness, and tensile strenght. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electroactive polymer cuff as taught by Banik, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

21. Regarding claims 45-48, Banik discloses the claimed invention but does not disclose expressly two tab coupling. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the single tab coupling as taught by Banik in figures 3a-4 with two tabs, because Applicant has not disclosed that two tabs provide an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a single tab as taught by Banik, because it provides a fastening means and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Banik.

Therefore, it would have been an obvious matter of design choice to modify single tab version of Banik with two tabs to obtain the invention as specified in the claim(s).

22. Regarding claim 49, Banik discloses that the polymer cuff includes sensors and a computer/controller for determining when to open or close the lumen (§ 115). It would have been obvious to one of ordinary skill in the art to modify the programming to control the cuff based on a cardiac signal since the cuff is designed to open and close a lumen based on a physiological signal and cardiac signals are physiological signals that can be sensed and be used to control a actuation of the cuff.

23. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banik as applied to claim 1 above, and further in view of Kim et al. (U.S. Pub. 2002/0092964 A1 hereinafter "Kim").

24. Regarding claims 14 and 15, Banik discloses the claimed invention except for the attachment of the first and second layers at a single point. Kim teaches that it is known to use electroactive polymers attached at a single point as set forth in Paragraph 34 and figures 1A and 1B to provide a way to expand and contract members. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electroactive polymer device as taught by Banik, with the single attachment point as taught by Kim, since such a modification would provide the device of Banik with a means for expanding and contracting from a single point for providing a means for engaging a lumen without fully encircling it.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes
Examiner
Art Unit 3762



George Evanisko
Primary Examiner
Art Unit 3762

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